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(72) MYERS, JAN WILLEM MARINUS (NL).

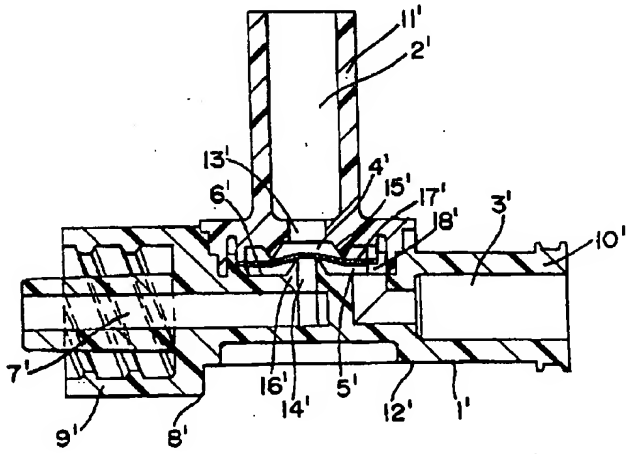
(73) FILTERTEK INC.
1411 Price Rd. P.O. Box 310 HEBRON XX (US).

(74) CASSAN MACLEAN

(54) ENSEMBLE POUR PERFUSION
(54) INFUSION SET

(57)

In an infusion set having a container for fluid medicines, which by a feed-line and a differential pressure valve is connected to a drip chamber and which by a further feed-line is connected to a front end controlled with a roller clamp according to U.S. Patent, 5,935,100, the differential pressure valve has two inlets each with an associated differential force chamber and the two differential force chambers are sealingly separated from each other by a diaphragm disk, sealingly separated from each other, wherein both differential force chambers are connected to an exit line for the fluid medicine. To use the differential pressure valve, the valve is configured as a 3-way check valve by the fact that the first inlet is connected to the container for the fluid medicine and that the second inlet is designed for the connection to a syringe or the like.



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(72) Inventeur/Inventor:
MYERS, JAN WILLEM MARINUS, NL

(73) Propriétaire/Owner:
FILTERTEK INC., US

(74) Agent: CASSAN MACLEAN

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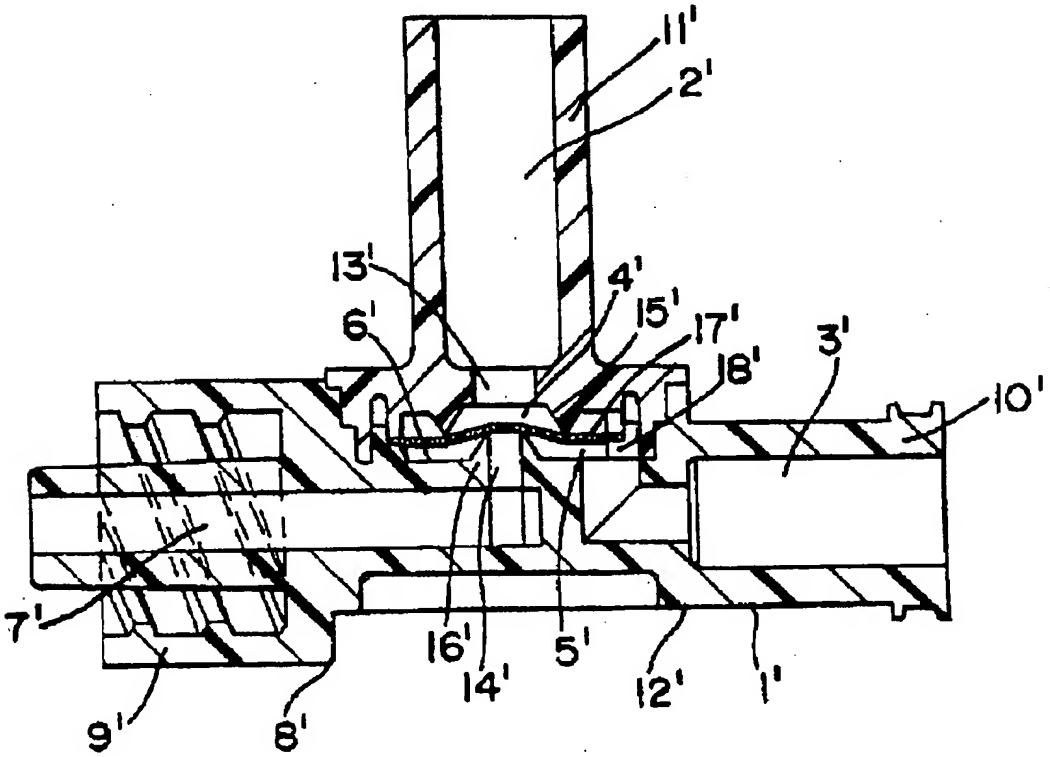

(57) Abrégé/Abstract:
In an infusion set having a container for fluid medicines, which by a feed-line and a differential pressure valve is connected to a drip chamber and which by a further feed-line is connected to a front end controlled with a roller clamp according to U.S. Patent, 5,935,100, the differential pressure valve has two inlets each with an associated differential force chamber and the two differential force chambers are sealingly separated from each other by a diaphragm disk, sealingly separated from each other, wherein both differential force chambers are connected to an exit line for the fluid medicine. To use the differential pressure valve, the valve is configured as a 3-way check valve by the fact that the first inlet is connected to the container for the fluid medicine and that the second inlet is designed for the connection to a syringe or the like.

Abstract of the Disclosure

In an infusion set having a container for fluid medicines, which by a feed-line and a differential pressure valve is connected to a drip chamber and which by a further feed-line is connected to a front end controlled with a roller clamp according to U.S. Patent, 5,935,100, the differential pressure valve has two inlets each with an associated differential force chamber and the two differential force chambers are sealingly separated from each other by a diaphragm disk, sealingly separated from each other, wherein both differential force chambers are connected to an exit line for the fluid medicine. To use the differential pressure valve, the valve is configured as a 3-way check valve by the fact that the first inlet is connected to the container for the fluid medicine and that the second inlet is designed for the connection to a syringe or the like.

INFUSION SET

Background of the Invention

Between the infusion containers and the drip chamber in general there is provided a valve for controlling the amounts. This function in the known valves is supplemented by the construction of the valve as check valves. Such check valves may contain a diaphragm disk (see, for example, DE 40 39 814 A1; DE 43 04 949 A1). Depending on the pressure on the front or rear sides of the diaphragm disk, a flow path is opened or closed permitting fluid to flow from the infusion containers.

The invention relates to an infusion set having a container for liquid medicines, which is connected to a drip chamber by a feed-line and a differential pressure valve and by a further feed-line connected to a front end being controlled by a roller clamp. A similar structure is disclosed in US Patent No. 5,935,100 (formerly US Patent Application Serial No. 08/800,779). In the disclosed structure, the differential pressure valve has two inlets, each with an associated differential force chamber, wherein the two differential force chambers are sealingly separated from each other by a diaphragm disk and, wherein further the two differential force chambers, together are connected to an exit line for the liquid medicine. The subject matter of US Patent 5,935,100 may be summarized as a method and infusion set for consecutively draining liquid medicines from a plurality of containers, such as two containers (1, 2) containing said liquid medicines, the liquid medicine via a differential pressure valve (5a) is fed into a drip chamber (6), wherein the fluid flow is permitted initially from one container (1) by the higher fluid pressure and differential force area from the first container (1) on a diaphragm disk (15), whereby the fluid flow from the second container (2) is stopped and, later an automatic switch to a second container (2) as a source of fluid is effected when the fluid flow from the almost drained first container (1) is at a lower fluid pressure and a smaller differential force area and is exceeded by a higher fluid pressure of the second container (2) and the larger differential force area.

In the infusion set according to US Patent No. 5,935,100 the differential pressure valve is performed such that it is used to empty sequentially a number of containers filled with liquid medicines in a controlled way.

In known infusion sets, an additional check valve is necessary to prevent a contamination of the set in the case of an occlusion or the like. Further, in many cases, it is necessary while the infusion is going on to administer additional amounts in a surge-like manner or to additionally inject, for example, contrast substances.

Summary of the Invention

In an infusion set of the present invention, this aim is achieved by the fact that the differential pressure valve is configured as a 3-way check valve

by the first inlet being connected to the container for the liquid medicine and by the second inlet being performed for the connection to a syringe or the like.

In an preferred embodiment according to the invention, the first inlet is provided with a male "Luer-Lock"-connector and the second inlet has a female "Luer-Lock"-connector.

According to a preferred embodiment of the invention, the valve comprises two valve housing halves being sealingly connectable with each other, wherein one valve housing half has the first inlet and the second valve housing half has the exit line and the second inlet.

In detail, it is of advantage that the two valve housing halves are connectable with each other. Within the differential force chambers each valve housing has an annular ridge concentric to a liquid inlet or liquid outlet, respectively, wherein the first inlet which is connected to the container is associated with an annular ridge having a larger diameter and the outlet line is associated with an annular ridge having a smaller diameter.

It is further preferred in this connection that the diaphragm disk with a part of its circumference is positioned at an opening which is leading to the second inlet.

A further improvement of the invention consists of the fact that the liquid outlet of the exit line coaxially opening to the annular ridge having the larger diameter has an angular shape and that the liquid inlet of the first inlet opening is coaxial to the other annular ridge and extends coaxially to the first inlet.

The desired valve action with an excellent sealing at very small pressures is achieved by the fact that the diaphragm disk has a circular shape and is manufactured from a sheet of liquid silicon, silicon or natural rubber or a strip of liquid silicon, silicon or natural rubber.

In one aspect of the invention, there is provided an infusion set having a container for liquid medicines, which is connected to a drip chamber by a feed-line and a differential pressure valve. The drip chamber is connected by a further feed-line to a front end with a roller clamp. A syringe is connected to the differential pressure valve. The differential pressure valve has a housing, a diaphragm disk retained about the perimeter thereof by the housing, a first inlet associated with a first inlet annular ridge and in fluid communication with the diaphragm disk, an outlet associated with an outlet annular ridge and in fluid communication with the diaphragm disk, and a second inlet in fluid communication with the diaphragm and the outlet annular ridge and the first inlet annular ridge. The differential pressure valve is configured as a 3-way check valve by the first inlet being connected to the container for the liquid medicine and the second inlet being configured for the connection to the syringe. Under normal valve operation the diaphragm is not sealingly engaging the first inlet annular ridge and the outlet annular ridge such that the first inlet is in fluid communication with the outlet. When pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the first inlet annular ridge. When negative pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the outlet annular ridge.

In another aspect of the invention there is provided a three way check valve adapted for connection to a container for liquid medicine, a syringe, and an outlet line. The valve comprises a housing, a diaphragm disk retained about the perimeter thereof by the housing, and a first inlet associated with a first inlet annular ridge and in fluid communication with the container for liquid medicine and the diaphragm disk. There is also an outlet associated with an outlet annular ridge and in fluid communication with the outlet line and the diaphragm disk. There is also a second inlet in fluid communication with the syringe and the diaphragm and the outlet annular ridge and the first inlet annular ridge. Under normal valve operation the diaphragm is not sealingly engaging the first inlet annular ridge and the outlet annular ridge such that the first inlet is in fluid

communication with the outlet. When pressure is created by the syringe at the second inlet and between the first inlet annular ridge and the outlet annular ridge, the diaphragm sealingly engages the first inlet annular ridge. When negative pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the outlet annular ridge.

In the following, the invention more detailedly is described with reference to the drawings.

Brief Description of the Drawings

FIG. 1 is a general side view of an embodiment of the assembled components for an infusion set;

FIG. 2 is a side view of an embodiment of a differential pressure valve with air relief lines;

FIG. 3 is a central axial cross-section of the differential pressure valve of FIG. 2;

FIG. 4 is a side view of an alternative embodiment of a differential pressure valve without air relief lines;

FIG. 5 is a central axial cross-section of the differential pressure valve of FIG. 4;

FIG. 6 is a central axial cross-section of another embodiment of a differential pressure valve that has a side view similar to that of FIG. 4;

FIG. 6a is a central axial cross-section of a component of the differential pressure valve of FIG. 6;

FIG. 6b is a plan view of the differential pressure valve component of FIG. 6a;

FIG. 7a is a central axial cross-section of a second component of the differential pressure valve of FIG. 6;

FIG. 7b is a plan view of the differential pressure valve component of FIG. 7a;

FIG. 8 is a central axial cross-section of another embodiment of the differential pressure valve that has a different first component than FIG. 6;

FIG. 8a is partially broken-out central axial cross-section of a first component of the differential pressure valve of FIG. 8;

FIG. 8b is a plan view of the differential pressure valve component of FIG. 8a;

FIG. 9 is a central axial cross-section of yet another embodiment of the differential pressure valve that has another first component than FIG. 6;

FIG. 9a is a central axial cross-section of a first component of the differential pressure valve of FIG. 9 before insertion of the injection site;

FIG. 9b is a plan view of the differential pressure valve component of FIG. 9a;

FIG. 9c is a central axial cross-section of the differential pressure valve component of FIG. 9;

FIG. 10 is a magnified partially broken out central axial cross-section of the embodiment of the differential pressure valve of FIGS. 8-9;

FIG. 11 is a cross-sectional view of the differential pressure valve in its embodiment as a 3-way check valve;

FIG. 12 is a bottom view of the valve of FIG. 11; and

FIG. 13 is an embodiment of the valve in its actual size.

Detailed Description of the Drawings and Preferred Embodiment of the Invention

In the drawings, the further constituents of the infusion set, namely, the container for the liquid medicines, the lines, the drip chamber, the roller clamp and so on are shown with reference to US Patent 5,935,100. The differential pressure valve of Figures 11, 12, and 13 forms the core of the present invention. Figures 1-10 are provided for background purposes to assist in the understanding of the contents of this document and is not meant to be taken or construed as prior art.

As shown in FIG. 1, a first container 1 is used for a chosen liquid medicine which can be different from the liquid medicine in a second container 2 or which can be the same. The liquid medicine is introduced by piercing means such as spikes 1a or 2a, respectively, that are for example from an ampulla. The first container 1 is connected to a first feed line 3 and the second container 2 is connected to a feed line 4 and both feed lines are connected to a valve 5 consisting of a differential pressure valve 5a more detailedly described below. The fluid medicine communicates with a drip chamber 6 via valve 5 and associated line and is under the control of a roller clamp 7 that in turn is fed to the front end 8 of the infusion set from where as usual it is introduced into the body of a patient.

One embodiment of a pressure differential valve is shown in FIGS. 2-3 and another embodiment, with similar features denoted by identical numerals, is shown in FIGS. 4-5. The liquid medicine is directed via the differential pressure valve 5 from the suspended containers 1 or 2 into the drip chamber 6. A feed line 3 of the first container 1 and a feed line 4 of the second container 2 leads to the differential pressure valve 5. Both feed lines 3 and 4 open into respective differential force chambers 13 and 14 which are sealingly separated from each other by the diaphragm disk 15. Both differential force chambers 13 and 14 are connected to a drain line 16 for the liquid medicine.

With reference to FIGS. 2-5, the differential pressure valve comprises two valve housing halves 9 and 10 which are adapted to sealingly contact each other, and after the mounting of the diaphragm disk 15 therein, the valve housing

halves 9 and 10 are sealed together thereby clamping securely diaphragm disk 15 therebetween. One of the valve housing halves, either half 9 or half 10, includes a drain line entry 11 for connection to an appropriate drain line 16, and each valve housing half 9 and 10 also includes a feed line entry 12. Valve housing halves 9 and 10 when assembled together with diaphragm disk 15 provide differential force chambers 13 and 14, respectively, within the valve. Annular ridge 18 of housing half 9 may, depending upon operating conditions as discussed below, establish a seal with diaphragm disk 15 that demarcates differential force chamber 13 into a circular chamber 13a and annular chamber 13b. Similarly, annular ridge 19 of housing half 10 may, again depending upon the operating conditions more fully explained below, establish a seal with diaphragm disk 15 that demarcates differential force chamber 14 into a circular chamber 14a and annular chamber 14b. Accordingly, the respective annular ridges 18, 19 may also be termed lip-shaped sealing rings 18, 19. Annular ridge 18 has a larger diameter than annular ridge 19.

Diaphragm disk 15 includes a perimeter portion 15a positioned at opening 20 that leads to the drain line 16. In this embodiment, diaphragm disk 15 is circular and produced from a sheet of liquid silicone, silicone rubber, or natural rubber or from a mat of liquid silicone, silicone rubber or natural rubber, and thus portion 15a is a part of the circumference of diaphragm disk 15. Further, opening 20 is in direct fluid communication with annular chamber 13b and annular chamber 14b irrespective of whether diaphragm disk 15 is sealed against annular ridges 18, 19. Also, in direct fluid communication with circular chambers 13a, 14a are fluid channels 17. In this embodiment, fluid channels 17 open coaxially to the respective circular chambers 13a, 14a and annular ridges 18, 19, and provide a fluid path that is at an angled shape, such as a 90° below.

In an alternative embodiment shown in FIG. 3, air relief lines 21 and 22, respectively, are connected to the fluid channels 17, wherein alternatively such air relief lines can be dispensed with in view of other well-known steps for air relief (see FIG. 5). In each of the air relief lines 21 and 22, respectively, there is inserted a hydrophobic filter diaphragm 23 which, on the one hand, is air-permeable but, on the other hand, is not permeable for liquids. The hydrophobic filter diaphragm may be a hydrophobic membrane ranging from 0.02 to 0.8 micron pore size.

The diaphragm disk 15 is preferably circular and stamped or die cut from a sheet or band of liquid silicone, silicone rubber, or natural rubber. The thickness of the diaphragm is preferably uniform and may vary, dependent on the desired pressure differential between chambers, from 0.2 to 0.5 mm. The thickness tolerance varies by the manufacturing method of the sheet or mat of the diaphragm material. The preferred embodiment consists of silicone rubber and has a diameter of about 13.5 mm, a thickness of about 0.3 mm, and a hardness of 40 degrees Shore A.

Further, the annular ridges 18, 19 or lip shaped sealing rings, are preferably about 60.degree. in cross-section and each ridge is integral with the respective housing half. The ratio of the diametric apex for the sealing ridge of ring 18 to the diametric apex for the sealing ridge or ring 19 is preferably chosen to be a ratio of about three to one. In this embodiment, it is thus believed that the hydrostatic pressure on the side of the diaphragm disk with the larger diametric apex for the sealing ridge must be less than one-third of the hydrostatic pressure of the fluid source associated with the sealing ridge with the smaller diametric apex before the diaphragm moves to open the side that engages the sealing ridge with the smaller diametric apex, and thus permit liquid to be transported to the patient from another fluid source associated with the smaller diametric apex sealing ridge.

Operation of the embodiments of the pressure differential valve is as follows. The fluid flow starts from the first container because of the higher fluid pressure and a larger differential force area of the first container 1 fluid via circular chamber 13a in front of the diaphragm disk 15 (see e.g., FIGS. 3 and 5) while the liquid flow from the second container 2 remains stopped because the larger differential force area prevents the flow of the liquid medicine from the second container 2. As soon as the liquid level of the first container and associated feed line decreases to a point where they are almost empty, the liquid pressure decreases such that the larger differential pressure area on the side of the diaphragm disk 15 corresponding to circular chamber 13a falls below the opening force created by the high fluid column of the second container 2 fluid via circular chamber 14a, whereby automatically liquid medicine flow is switched over from the first container 1 to the second container 2.

Accordingly, the use of the above-described infusion set embodiment may

occur for example when using consecutively two infusion solutions to be administered to a patient. Under such use conditions, and during the liquid flow from the first container 1, the liquid flow may suck air from the area of the second container 2, which possibly has to be vented. Thereafter the roller clamp 17 may be adjusted to the desired dripping rate, and the first container is emptied whereafter the switch over to the second container occurs automatically. At the time of the automatic switch over and thereafter during the fluid flow operation, there is an overpressure of the fluid flow from the second container 2, and the diaphragm disk 15 is pressed onto the annular ridge 18 and also is lifted from the annular ridge 19 such that the liquid medicine can drain from the second container 2 to the patient.

An alternative embodiment is shown in FIGS. 6-7b, in which like reference numerals indicate like parts and features as the above figures. Primary housing half 60 and secondary housing half 30 are sealingly engaged. Like the other embodiments, one housing half includes annular ridge 18 provided with a sealing lip apex 18a and the other housing half is provided with annular ridge 19 that includes sealing lip apex 19a. Secondary housing 30 (see FIGS. 6a-6b) is provided with inlet 17a, about which is located annular ridge 18. Secondary housing 30 includes a compression ring 32 that projects from the secondary housing 30 body and has a diameter greater than annular ridge 18. Compression ring 32 is provided with compression ring passage 34, that in conjunction with valve space passage 64 (discussed below) allows for fluid communication between annular chambers 13b and 14b in the assembly of the housing halves 30, 60. Secondary housing 30 is further provided with first sealing ring projection 36 that has a diameter greater than that of the compression ring 32 and allows for sealing engagement of the housing halves. Secondary housing 30 may also have a secondary sealing ring 38 that may provide an alternative sealing engagement member for the assembly.

Primary housing half 60 (see FIGS. 7a-7b) is provided with inlet 17b about which is located annular ridge 19, that in turn includes sealing lip apex 19a. Outside of annular ridge 19 is located opening 20 that is in fluid communication with drain line 16 (see FIGS. 7a-7b). Encircling annular ridge 19 and opening 20 is ring shaped seat 62 that is discontinuous and provided with a valve space passage 64. Ring shaped seat 62 is adapted to clamp diaphragm disk 15

between ring shaped seat 62 and compression ring 32 when the housing halves are assembled (see FIG. 6). Encircling ring shaped seat 62 is sealing ring projection 66 which is continuous and adapted to engage first sealing ring projection 36 of the secondary housing when the housing halves are assembled. Intermediate sealing ring projection 66 and ring shaped seat 62 is secondary sealing ring 68 that is of sufficient height to allow for the fluid communication between compression ring passage 34 and valve space passage 64 when the housing halves are assembled. The aforementioned combination of the valve space passage 64 overlying compression ring passage 34 provides a bypass channel 70 in the assembled housing halves (see FIG. 6). This bypass channel 70 is generally radial in configuration in this embodiment, and the overlying radial passages 34 and 64 are assured in the assembly by way of orienting the respective feed line entry 12 passage in a parallel condition.

In the assembly of the housing halves, the housing halves are sealed together at the interface between the first sealing ring projection 36 and sealing ring projection 66, which in turn clamps the diaphragm 15 between ring shaped seat 62 and compression ring 32. Such joinder may be executed by means of ultrasonic welding or use of medically approved adhesives (e.g., ultraviolet curing adhesives), or a combination thereof. The presently preferred sealing means employs ultrasonic welding. The clamped interface between the disk 15, ring shaped seat 62 and compression ring 32 may also be executed by means of ultrasonic welding or use of medically approved adhesives.

An alternative secondary housing half 40 is shown in FIGS. 8a-8b, that in turn may be assembled with primary housing half 60. This assembly is shown in FIG. 8. Referring now in more detail to these drawings, in which like reference numerals indicate like parts and features throughout the several of the above-discussed views, secondary housing 40 (see FIGS. 8a-8b) is generally provided with a threaded connection 41 for connecting the housing half 40 to an appropriate liquid medicine feedline. With this design, there is thus the possibility to connect the housing half by means of a male luerlock connection or other medically accepted threaded connection.

Further, alternative secondary housing 40 includes a compression ring 42 that projects from the housing 40 that is a diameter greater than annular ridge 18. Secondary housing 40 is further provided with sealing ring projection 46, of a

diameter greater than compression ring 42 that permits sealing engagement between housing halves, and secondary sealing ring 48 may provide an alternative sealing engagement for the assembly. Compression ring passage 44, in this embodiment, is generally radial and allows for fluid communication between the annular chamber 13b and annular channel 80 provided in secondary housing 40. Thus, in this embodiment of the secondary housing, when assembled with primary housing 60, fluid communication between secondary housing inlet 17a and outlet opening 20 is permitted at an appropriate pressure differential between chambers 13 and 14 via fluid passage over sealing lip 18a, and through annular chamber 13b, compression ring passage 44, annular channel 80, valve space passage 64 and annular chamber 14b (see FIG. 10). Of note for this embodiment is that a bypass channel generally denoted 82 formed by the assembly does not require that passages 64, 44 overlie one another due to the provision of annular channel 80. Accordingly, annular channel 80 permits greater tolerances in angular orientation of secondary housing 40 with respect to primary housing 60, and thus this design may be more suitable for automatic assembly. For this reason, among others, bypass channel 82, including annular channel 80, may be preferably utilized in the above-described secondary housing 30, as well as 40, and 50 to which discussion is now directed.

Another alternative embodiment of a differential pressure valve is shown in FIGS. 9-9c. Referring now in more detail to these drawings, in which like reference numerals indicate like parts and features throughout the several above-discussed views, there is provided an assembly that is a differential pressure valve that incorporates an alternative secondary housing 50. Alternative secondary housing 50 is provided with a plurality of inlet passages 17c that are in fluid communication with injection site 58. In the preferred embodiment, the injection site 58 is secured by annular shoulder 52 and annular rim 54. In its embodiment, injection site 58 consists of natural rubber of 60.degree. Shore.A hardness which is secured in alternative secondary housing 50 by friction rolling or ultrasonics. Rim 54 is formed by either such means due to the raised temperature in combination with the axial compression inherent with these means (see FIG. 9a). In other respects, alternative secondary housing 50 is constructed and assembled like the embodiments immediately described above (see FIG. 10). As can be readily appreciated, the alternative embodiment of the

differential pressure valve permits the injection of one or more liquids via a hypodermic needle or the like introduced through the injection site 58. By way of the appropriate pressure differential from the hypodermic needle fluid, liquid medicine from the needle or the like may be introduced into the fluid flow.

In the embodiments of the differential pressure valves, the valve housings may be manufactured of polymeric materials that are generally medically accepted, e.g. polystyrenes, styrenic copolymers (A.B.S.) or polycarbonates. In particular, the preferred material is a styrenic copolymer (A.B.S.) manufactured by BASF Corporation, and sold under the trademark name of Terlux KR2802.

In one embodiment for the differential pressure valve differential force chambers 13, 14, including circular chambers 13a, 14a and annular chambers 13b, 14b, are as follows. With respect to the primary housing 60 (FIGS. 7a-7b), housing inlet 17b is about 2.0 mm and opening 20 for drainline 16 has a diameter of about 2.0 mm. Sealing lip apex 19a which engages diaphragm disk 15 when the differential pressure in circular chamber in 14a is insufficient, has a diameter of about 3.0 mm. In radial dimensions (see FIG. 7b), ring shaped seat 62 has a beginning diameter of about 12.0 mm and terminates at a diameter of about 13.6 mm, at which point it rises axially to the secondary sealing ring 68 and this surface extends to a diameter of about 16.0 mm. At the termination of secondary sealing ring 68, sealing ring projection 66 axially rises and continues from about 16.0 to a diameter of about 18.0 mm. In axial cross-sectional dimensions, and with reference to a datum from the sealing ring projection 66 plane (i.e., the left most edge of the housing half depicted in FIG. 7a), the secondary sealing ring 68 plane is about 0.68 mm from the sealing ring projection 66. Further, and with respect to this datum, ring shaped seat 62 is about 1.84 mm from the sealing ring projection 66, and further, the member that forms the annular chamber 14b is about 2.40 mm from this datum. Annular ridge 19 in cross-section is about 60.degree. and sealing lip apex 19a is located about 1.54 mm from the datum of the sealing ring projection 66 plane.

The secondary housing half is configured as follows, with particular reference to the features forming circular chamber 13a and annular chamber 13b of the pressure differential valve (see FIGS. 6a, 6b, 8a, 8b, 9a-9c, 10). Inlet 17a is about 2.0 mm in diameter, and sealing lip apex 18a has a diameter of about 9.0 mm. Compression ring 32 has an inner diameter of about 12.0 mm and an

outer diameter of about 13.6 mm. Secondary sealing ring 38 has an outside diameter of about 16.0 mm and inside diameter of about 15.0 mm, and first sealing ring projection 36 has an outside diameter of about 18.0 mm. In axial dimensions, and with reference to the datum of the leading edge of compression ring 32 (the rightmost edge as viewed in FIGS. 6a, 8a and the uppermost edge as viewed in FIGS. 9a, 9c), the sealing lip apex 18a is at about the same plane as compression ring 32 plane, and apex 18a has an angular cross-section of about 60.degree. The plane of the secondary sealing ring 38 is about 0.86 mm from the datum of the compression ring 32, as is the floor of the circular chamber 13a. The plane of the first sealing ring projection 36 is about 1.54 mm from the datum of the plane of the compression ring 32, as is the plane of annular passage 80. Further, the compression ring passage 34 and valve space passage 64 may overlie one another and are of about 2.0 mm in width (see FIGS. 6b, 8b, 9b). As noted above, however, for configurations that include annular channel 80, passages 34, 64 need not overlie each other.

As especially can be seen in Figure 11, the preferred valve 1' has two inlets 2' and 3', which each are open to a differential pressure chamber 4' or 5', respectively. The two differential pressure chambers 4' and 5' are sealingly separated from each other by a diaphragm disk 6. Both differential pressure chamber 4' and 5' together are in communication with an exit line 7' for the liquid medicine, wherein the exit line 7' is usually connected to the line leading to the drip chamber, while the first inlet is usually connected to the flask or container of the liquid medicine by means of a suitable line.

As shown in FIGS. 11-13, the exit line 7' has a male "Luer-Lock"-connector 9' and the second inlet 3' has a female "Luer-Lock"-connector 10, wherein the sizes are chosen such that by means of the slight tapering of the second inlet 3', the front end of a typical syringe can be received in a form-fit manner.

The housing of the differential pressure valve 1' is made of two valve housing halves 11' and 12', which are sealingly connectable with each other. The valve housing half 11' contains the first inlet 2' and the second valve housing half 12' contains the second inlet 3' and the exit line 7'. The valve housing half 11' has an annular ridge 15' within the differential force chamber 4', the ridge 15' being concentric to a liquid inlet 13'. The valve housing half 12' has an annular ridge 16' within the differential force chamber 5', concentric to a liquid outlet 14'.

The sizes of ridges 16' and 15' are such that the annular ridge 15' has a larger diameter, and is associated with the first inlet 2', which is connected to the container for the liquid medicine. The annular ridge 16', having a smaller diameter, is associated with the exit line 7' leading to the drip chamber.

The diaphragm disk 6' is positioned between the two housing halves 11' and 12' with a part 17' of its circumference lying at an opening 18' leading to the second inlet 3'. The liquid outlet 14' of the exit line 7' has an angular shape and is coaxial to the annular ridge 16' as shown in FIG. 11. The liquid inlet 13' of the inlet 2' is coaxial to the annular ridge 15', which is also coaxial to the inlet 2'.

The circular diaphragm disk 6' is manufactured from a sheet of liquid silicone, silicone or natural rubber or a strip of silicone, liquid silicone, silicone or natural rubber.

The operation of the 3-way check valve 8' is such that during a normal infusion, the infusion liquid is guided from the inlet 2', to the outlet line 7'. If liquid medicine is drawn from the container of the liquid medicine by means of a syringe at the inlet 3', the diaphragm 6' is pressed against the annular ridge 16' because of the vacuum created on the bottom side, which means that liquid is not drawn from the line 7' leading to the patient. If, on the other hand, additional liquid or possibly a different medicine is injected at the second inlet 3', then because of the correspondingly created pressure, the diaphragm disk 6' is pressed against the upper annular ridge 15', which means that the additional liquid is guided exclusively via the exit line 7' from the second inlet 3' to the patient, and cannot reach the line leading back to the container connected to the first inlet 2'.

The preferred embodiment of the invention thus provides an extremely compact 3-way check valve which consists merely of three parts, namely, the first valve housing half 11', the second valve housing half 12', and the diaphragm 6' positioned therebetween.

The features disclosed in Figures 1-10 and discussed above has been patented in US patent 5,935,100.

It is of note that the above-described pressure differential valve has numerous advantages. The disclosed valve is of simple construction, yet provides a reliable valve for operating pressures to which it is suited. It is believed that with the construction of this pressure differential valve as disclosed, the tension in the diaphragm disk can be accurately predetermined and provide automatic switching between fluid sources at predetermined hydrostatic pressures. In this manner, the present invention avoids complicated designs and yet may result in reliably achieving the above-noted pressure differential valve functionality. Further, the design of the above-described embodiments avoids complicated assembly methods by way of limiting the number of highly toleranced dimensions or assembly methods and the like and thus they lend themselves to assemblage by automated equipment.

While the above embodiments of the inventions have been disclosed, they are not limited to the disclosed examples. Modifications discussed above, as well as in addition to those discussed, can be made without departing from the inventions. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein. Thus, while the inventions have been described with reference to particular embodiments, modification of structure, material and the like will be apparent to those skilled in the art, yet still fall within the scope of the invention.

All features, details and advantages of the invention, which can be learned from the specification, the claims, and the drawings, including constructive details and positions in space, can be important for the invention each singularly as well as in random combination.

WHAT IS CLAIMED IS:

1. An infusion set having a container for liquid medicine, which is connected to a drip chamber by a feed-line and a differential pressure valve, the drip chamber connected by a further feed-line to a front end with a roller clamp, and a syringe connected to the differential pressure valve, characterized in that the differential pressure valve having a housing, a diaphragm disk retained about the perimeter thereof by the housing, a first inlet associated with a first inlet annular ridge and in fluid communication with the diaphragm disk, an outlet associated with an outlet annular ridge and in fluid communication with the diaphragm disk, and a second inlet in fluid communication with the diaphragm and the outlet annular ridge and the first inlet annular ridge, wherein the differential pressure valve is configured as a 3-way check valve by the first inlet being connected to the container for the liquid medicine and the second inlet being configured for the connection to the syringe whereby under normal valve operation the diaphragm is not sealingly engaging the first inlet annular ridge and the outlet annular ridge such that the first inlet is in fluid communication with the outlet, and when pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the first inlet annular ridge, and when negative pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the outlet annular ridge.

2. The infusion set according to claim 1, further characterized in that the outlet comprises a male "Luer-Lock"-connector or the second inlet comprises a female "Luer-Lock"-connector.

3. The infusion set according to claim 1, further characterized in that the differential pressure valve comprises a first valve housing half and a second valve housing half connected with each other with the diaphragm disk

therebetween, wherein the first valve housing half comprises the first inlet and the second valve housing half comprises the outlet and the second inlet.

4. The infusion set according to claim 3, further characterized in that the first valve housing half comprises the first inlet annular ridge with the first inlet annular ridge concentric to the first inlet, and the second valve housing half comprises the outlet annular ridge, with the outlet annular ridge being concentric to the outlet, and wherein the first inlet, which is connected to the container, is associated with an annular ridge having a first diameter, and wherein the outlet is associated with an annular ridge having a smaller diameter than said first diameter.

5. The infusion set according to claim 3, further characterized in that the diaphragm disk is positioned between the first valve housing half and the second valve housing half, with a part of the diaphragm disk circumference at an opening leading to the second inlet.

6. The infusion set according to claim 4, further characterized in that the outlet annular ridge is oriented coaxially to the first inlet annular ridge.

7. The infusion set according to claim 1 further characterized in that the diaphragm disk has a circular shape and is produced from a liquid silicone, silicone or natural rubber sheet or a liquid silicone, silicone or natural rubber strip.

8. The infusion set according to claim 7, further characterized in that the outlet annular ridge has a diameter, and the first inlet annular ridge has a diameter and wherein the outlet annular ridge diameter is smaller than the first inlet annular ridge diameter.

9. The infusion set according to claim 8, further characterized in that the outlet annular ridge is coaxial with the first inlet annular ridge.

10. The infusion set according to claim 9, further characterized in that the differential pressure valve comprises a first valve housing half and a second valve housing half sealed together with the diaphragm disk therebetween.

11. The infusion set according to claim 10, wherein the first valve housing half comprises the first inlet and the second valve housing half comprises the outlet and the second inlet.

12. The infusion set according to claim 11, wherein the outlet comprises a male luer lock connector or the second inlet comprises a female luer lock connector.

13. A three way check valve adapted for connection to a container for liquid medicine, a syringe, and an outlet line, comprising a housing, a diaphragm disk retained about the perimeter thereof by the housing, a first inlet associated with a first inlet annular ridge and in fluid communication with the container for liquid medicine and the diaphragm disk, an outlet associated with an outlet annular ridge and in fluid communication with the outlet line and the diaphragm disk, and a second inlet in fluid communication with the syringe and the diaphragm and the outlet annular ridge and the first inlet annular ridge, whereby under normal valve operation the diaphragm is not sealingly engaging the first inlet annular ridge and the outlet annular ridge such that the first inlet is in fluid communication with the outlet, and when pressure is created by the syringe at the second inlet and between the first inlet annular ridge and the outlet annular ridge, the diaphragm sealingly engages the first inlet annular ridge, and when negative pressure is created by the syringe between the first inlet annular ridge and the outlet annular ridge the diaphragm sealingly engages the outlet annular

ridge.

14. The three way check valve of claim 13, wherein the outlet annular ridge diameter is smaller than the first inlet annular ridge diameter.

15. The three way check valve according to claim 14, further characterized in that the outlet annular ridge is coaxial with the first inlet annular ridge.

16. The three way check valve of claim 15, wherein the diaphragm disk is produced from a liquid silicone, silicone or natural rubber sheet or a liquid silicone, silicone or natural rubber strip.

17. The three way check valve according to claim 16, further characterized in that the three way check valve comprises a first valve housing half and a second valve housing half sealed together with the diaphragm disk therebetween.

18. The three way check valve according to claim 17, wherein the first valve housing half comprises the first inlet and the second valve housing half comprises the outlet and the second inlet.

19. The three way check valve according to claim 18, wherein the outlet comprises a male luer lock connector or the second inlet comprises a female luer lock connector.

20. The three way check valve according to claim 19, wherein the diaphragm disk is positioned within the housing such that a portion of its circumference is located at an opening leading to the second inlet.

CASSAN MACLEAN
Suite 401, 80 Aberdeen Street
Ottawa, Ontario
K1S 5R5

Agents for the Applicant

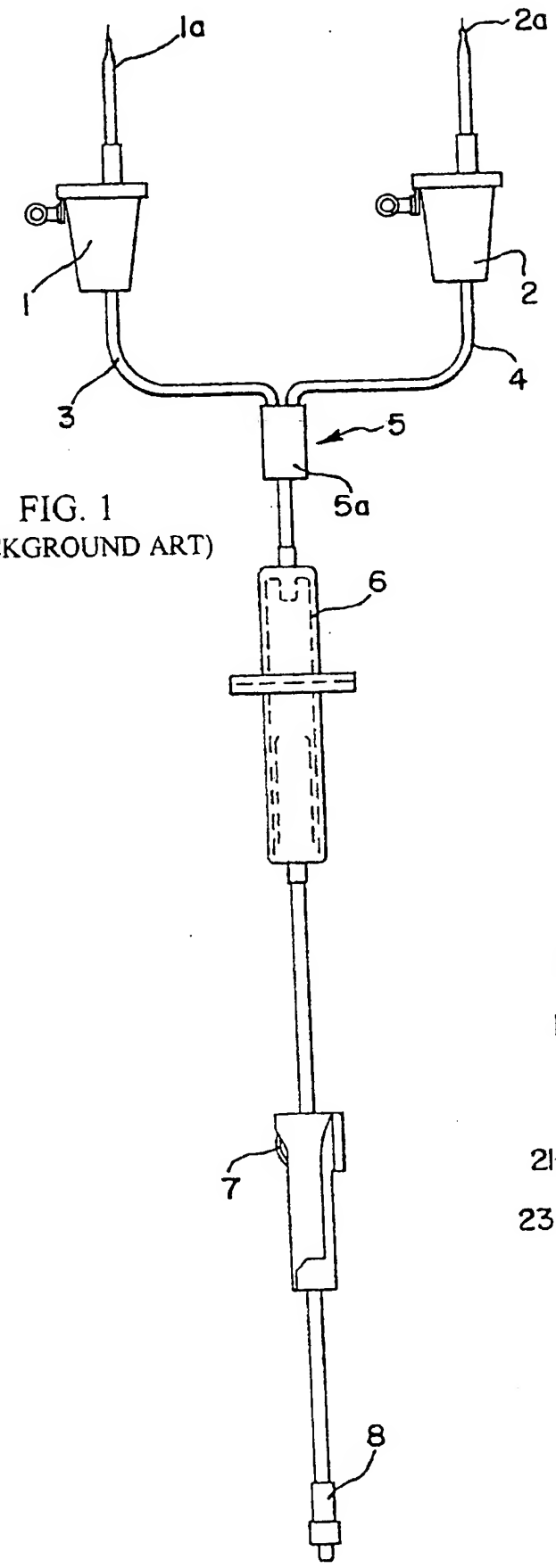

FIG. 1
(BACKGROUND ART)

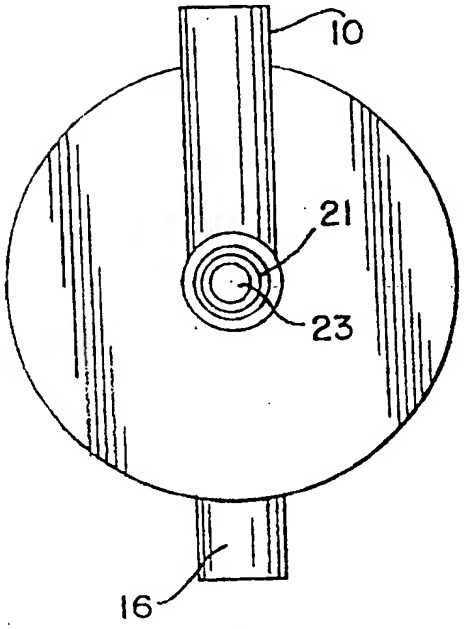

FIG. 2
(BACKGROUND ART)

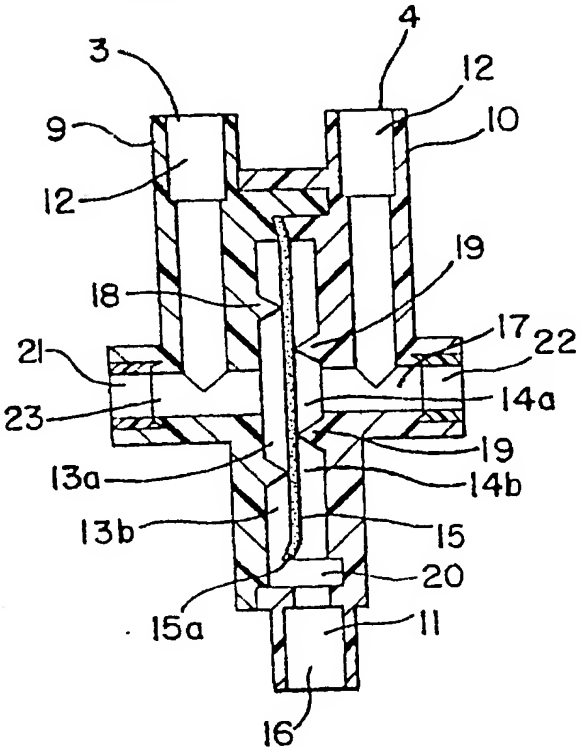

FIG. 3
(BACKGROUND ART)

FIG. 4
(BACKGROUND ART)

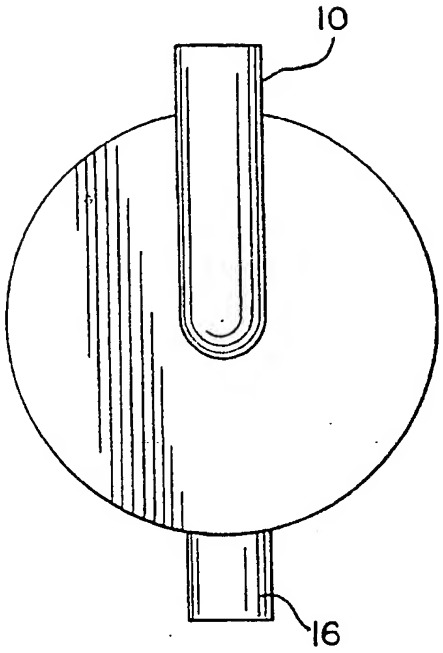

FIG. 5
(BACKGROUND ART)

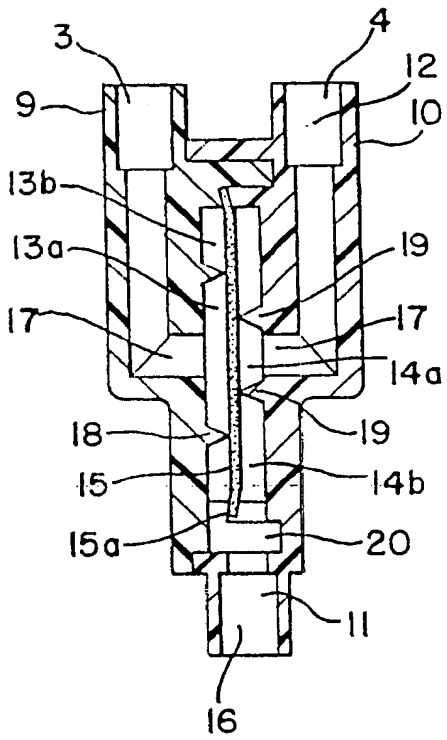

FIG. 6
(BACKGROUND ART)

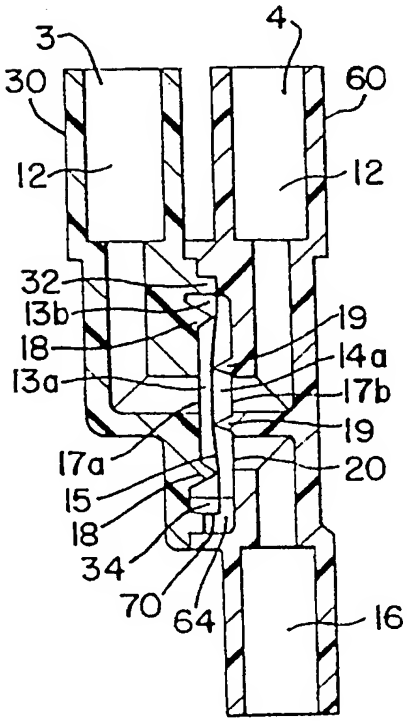

FIG. 6a
(BACKGROUND ART)

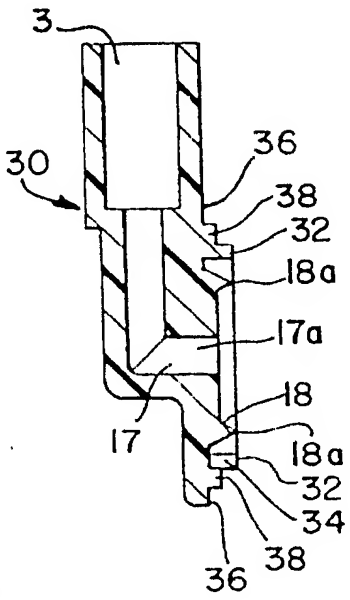

FIG. 6b
(BACKGROUND ART)

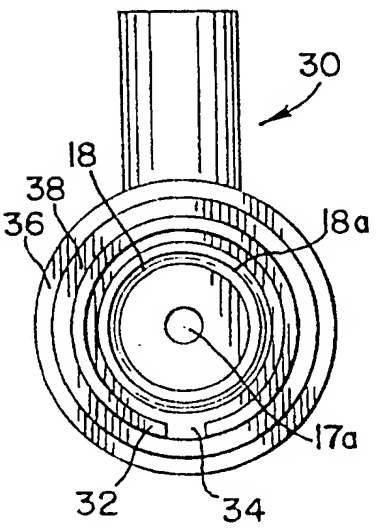

FIG. 7b
(BACKGROUND ART)

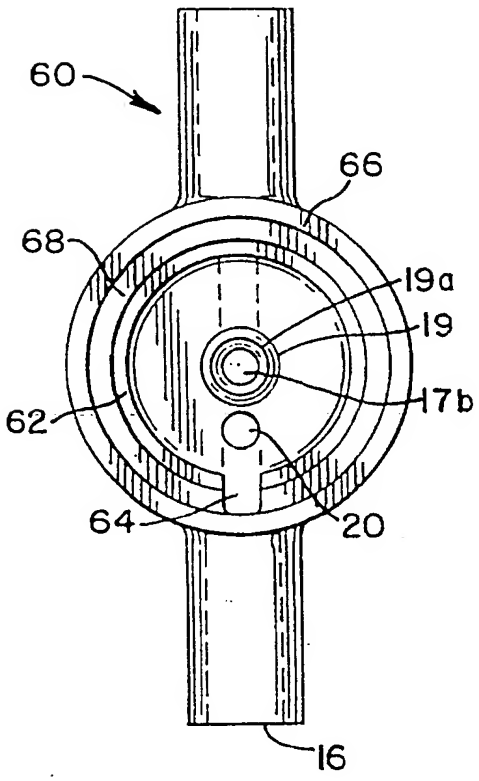

FIG. 7a
(BACKGROUND ART)

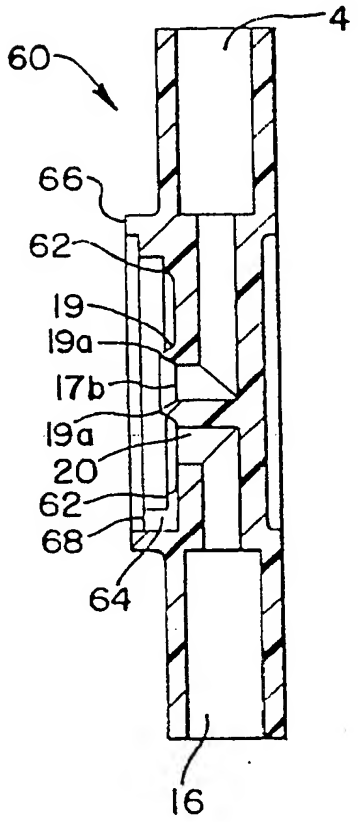

FIG. 8
(BACKGROUND ART)

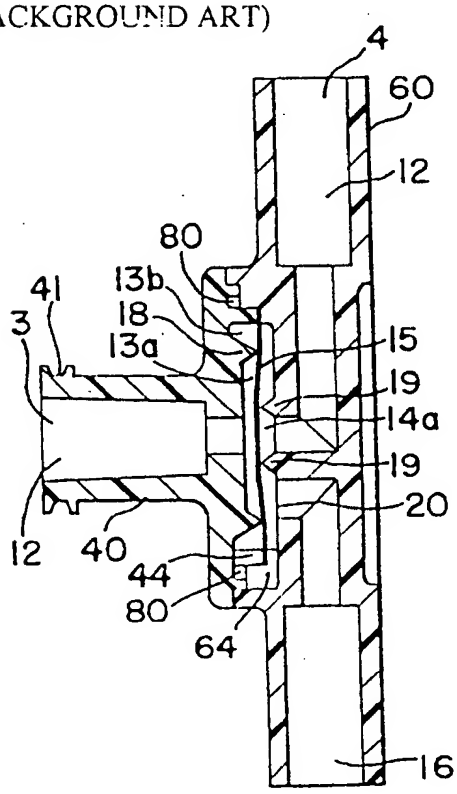

FIG. 8a
(BACKGROUND ART)

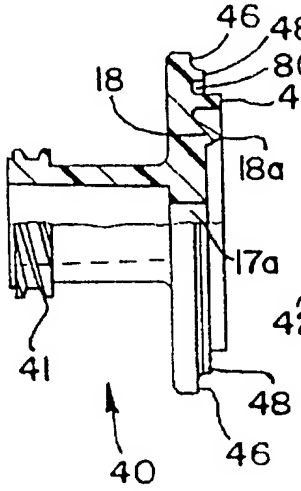

FIG. 8b
(BACKGROUND ART)

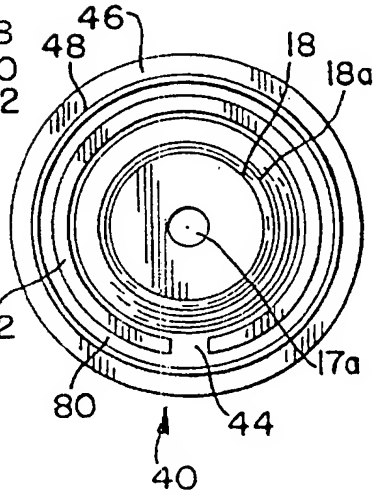

FIG. 9
(BACKGROUND ART)

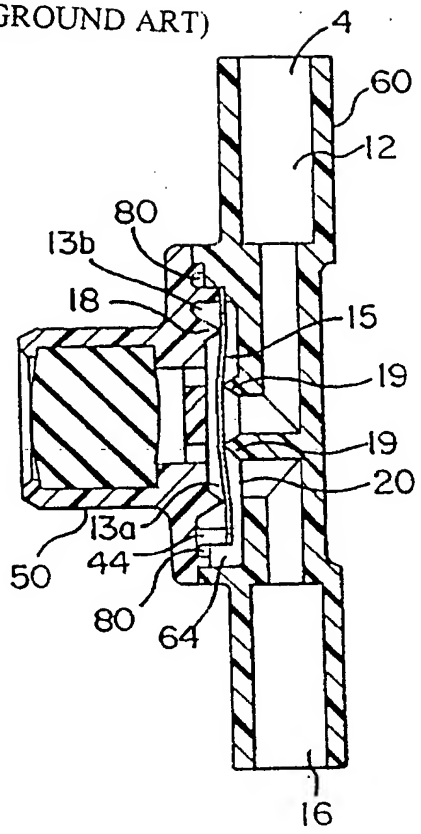

FIG. 10
(BACKGROUND ART)

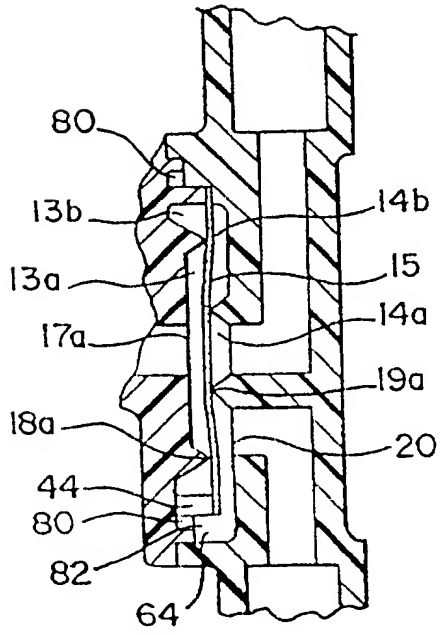

FIG.11

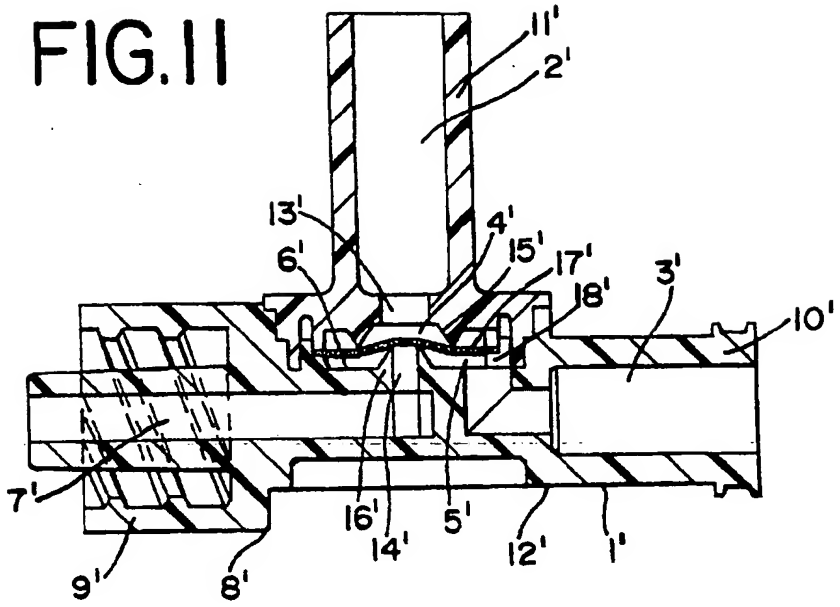

FIG.12

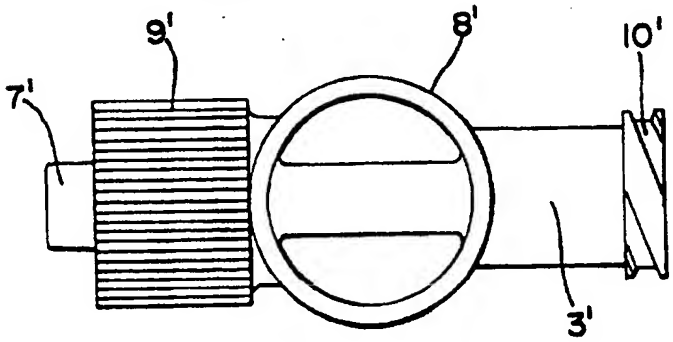

FIG.13